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Customer No. 23932

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:)
)
Richard J. Lazzara)
Thomas S. Heylmun)
Keith D. Beaty)
)
Application No.: 09/237,605)
)
Filed: January 25, 1999)
)
For: Infection-Blocking Dental Implant)

Atty. Docket No.: 47168-00035USC1

Examiner: Paul Prebilio

Group Art Unit: 3738

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| <p align="center">CERTIFICATE OF MAILING</p> <p>I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on August 6, 2001.</p> <p>Signature: <u>Deborah Ricks</u> Debra Ricks</p> |
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**THIRD INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. §§ 1.97 AND 1.98**

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Third Information Disclosure Statement be entered, and the references listed on enclosed Form PTO-1449 be considered by the Examiner and made of record. In accordance with 37 C.F.R. § 1.98(d), copies of the listed references are enclosed.

In accordance with 37 C.F.R. §§ 1.97(g) and (h), this Third Information Disclosure Statement is not to be construed as a representation that a search has been made, or an admission that the information disclosed is, or is considered to be, prior art with respect to the present application or material to patentability, as defined in 37 C.F.R. § 1.56.

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The items listed on Form PTO-1449 are from Friatec Inc. (a.k.a. Friadent and Friedrichsfeld). All of them relate to a stepped-screw dental implant marketed under the name "Frialit®-2 Stepped Screw." The Frialit®-2 Stepped Screw has a surface referred to as the "Frios® Deep Profile Surface" made in accordance with a "Deep Profiling Method" that includes a "proprietary grit blasting and acid-etching procedure." While many of these items are not *per se* prior art, they provide insight into Friatec's development and commercialization of the Frialit®-2 Stepped Screw in the 1990's. The items have been organized in a chronological fashion and will be explained. The Examiner, of course, is encouraged to review each of these items in detail to reach his or her own conclusions about these references.

Reference C39 is a 1992 article that discusses the development of the Frialit®-2 system. The publishing of this article appears to have coincided with the European release of the Frialit®-2 system in 1992 (Reference C42, p. 2). The 1992 article mentions that the process used to develop the implant surfaces in FIGS. 13 and 14 includes sand blasting and etching. Reference C39, p. 8. The caption under FIG. 13 suggests that the sand blasting includes the use of aluminum oxide powder. No details are provided on how the sand blasting process and the etching process were conducted to achieve the disclosed surface.

Reference A53 is U.S. Patent No. 5,199,873 assigned to Friedrichsfeld, which is believed to be the former name of Friatec. The '873 patent issued in 1993 and claims priority to a German application filed on January 15, 1990. The '873 patent was discovered in a patent search that was conducted to learn whether the details of the grit-blasting procedure and acid-etching procedure of the "Deep Profiling Method" were, perhaps, disclosed in a U.S. patent or a European patent/published application assigned to Friatec, Friadent, or Friedrichsfeld. The '873 patent discloses and claims the configuration of the Frialit®-2 Stepped Screw. While it appears

from the other references discussed therein that the Frialit®-2 Stepped Screw was commercially offered with the microstructure known as the Deep Profile Surface, the '873 patent fails to disclose any details concerning the microstructure of this implant.

Reference C40 is 1996 product literature from Friatec and Interpore International, the initial U.S. distributor for the Frialit®-2 implant system. It mentions that the Frialit®-2 implant system would be commercially available in the U.S. in April 1996. One of the implants is the Stepped Screw having the "Frios® Deep Profile Surface." No details are provided on how this Deep Profile Surface is made.

Reference C41 is a 1997 article that discusses the alleged efficacy of the Frialit®-2 implant. Again, no details are provided on how to achieve the surface on the Frialit®-2 Stepped Screw.

Reference C42 is product literature believed to be dated in 1996 or 1997 from Friatec and Interpore International which states that the Stepped Screw has a surface roughened from the Frios® Deep Profiling Method. Reference C42, p.5. No details are provided on this method.

Reference C43 is an article written sometime after June 6, 1998, that is present on Friatec's website (<http://www.friatec-med.com/divisionuk/divmed/emda/emdaframe.htm>). Its date of publication is unknown. The reason it is known to be written after June 6, 1998, however, is that it refers to an article from June 6, 1998, in footnote 34. At page 6, it mentions that the grit blasting is performed by "a certain technique," but fails to provide any description of that "certain technique." It further mentions that the etching is performed with "mineral acids," but mentions none of the details of the etching process (e.g., etching times, acid concentrations, etc.) or even which type (or types) of mineral acids are being used.

Reference C44 is an October 1998 Price List from Friatec that discloses the Stepped Screw having the "Frios® Deep Profile Surface." Reference C44, p. 4. No details are provided on how this Deep Profile Surface is made.

Reference C45 is Friadent Product Literature from February 1999 that discloses the Stepped Screw having the "Frios® Depth Structuring" surface, which is sand-blasted and acid-etched. Reference C45, p.6. No details are provided on the sand blasting and acid-etching processes.

Reference C46 is a September 2000 Price List from Friadent that discloses the Stepped Screw having the "Frios® Deep Profile Surface." Reference C46, p. 7. No details are provided on how this Deep Profile Surface is made.

Reference C47 is Product Literature from Friadent believed to be dated in 2000. As Reason No. 7 from the "The Top Ten Reasons To Use Frialit-2," Friadent states that "[t]he Stepped Screw surface is treated with the Deep Profiling Method. This proprietary grit blasting and acid-etching procedure greatly increases the surface area and enhances the bone-implant interface." (emphasis added) The fact that Friadent considers the Deep Profiling Method procedure to be "proprietary" suggests the reason that the aforementioned references attributed to Friatec fail to disclose any details about this surface treatment procedure -- Friatec apparently considers this procedure to be a trade secret.

Consequently, it appears that Friatec purposefully did not disclose any details of the processes it used to create the microstructure on the Frios® Deep Profile Surface that are shown in various pages of the aforementioned references. Further, it is unclear whether the microstructure on the Frios® Deep Profile Surface or method for producing this microstructure was consistent throughout the 1990's.

A reference cannot anticipate that which it does not enable. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 665 (Fed. Cir. 1986); MPEP §2121. It has been long established that a prior reference must contain "such full, clear, and exact terms as to enable any person skilled in the art . . . to make, construct, and practice the invention . . ." *Seymour v. Osborne*, 78 U.S. 516, 555 (1870). "Mere vague and general representations" will not suffice; the reference must "be an account of a complete and operative invention capable of being put into practical operation." *Id.* Because of the numerous details involved with both the grit-blasting process and the etching process that a skilled artisan must know to attain the Frios® Deep Profile Surface, these Friatec references are not enabling. In fact, Friatec's apparent suppression and concealment of its surface treatment methodology (or methodologies) is the antithesis of providing an enabling disclosure. As such, to the extent that any of these Friatec references predate the effective filing date of any of the pending claims in the present application, they are not useful for rendering the pending claims unpatentable.

If the Examiner disagrees with this analysis regarding the lack of enablement in these Friatec references, the Applicant respectfully requests that the Examiner explain his or her position in the next official paper. Of course, if the Examiner has questions about these references or wishes to discuss this enablement issue, the Examiner is invited to contact the Applicant's representative at the number listed below.

This Third Information Disclosure Statement is being filed after the mailing of either a final Office Action or a Notice of Allowance but before payment of the issue fee. Accordingly, enclosed is Check No. 27004 in the amount of \$180.00 for the petition fee set forth in 37 C.F.R.

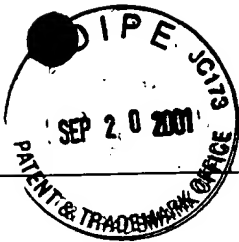
§ 1.17(i). If any additional fees are due, please charge Deposit Account No. 10-0447 (47168-00035USC1). A duplicate copy of this Statement is enclosed for that purpose.

Respectfully submitted,

Date: August 6, 2001



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Form PTO-1449 (modified)

LIST OF ART CITED BY APPLICANT

Sheet 1 of 1

Application No.: 09/237,605

Filing Date: January 25, 1999

First Named Inventor: Richard J. Lazzara

Group Art Unit: 3738

Examiner: Paul Prebilio

Attorney Docket No.: 47168-00035USC1

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U.S. PATENT DOCUMENTS

| Examiner Initial | Ref. | Document Number | Date | Name | Class | Sub-Class | Filing Date (if Application) |
|------------------|------|-----------------|----------|----------------|-------|-----------|------------------------------|
| | A40 | 5,199,873 | 04/06/93 | Schulte et al. | 433 | 174 | |
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FOREIGN PATENT DOCUMENTS

| Examiner Initial | Ref. | Document Number | Date | Country | Class | Sub-Class | Translation Yes/No |
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OTHER DOCUMENTS (including author, title, date, pertinent pages, etc.)

| Examiner Initial | Ref. | Document Information |
|------------------|------|--|
| | C36 | Schulte, W., et al., "The First 15 Years Of The Tuebinger Implant And Its Further Development To The Frialit®-2 System," Zeitschrift für Zahnärztliche Implantologie, Band VIII, cover page, pp. 3-22 (February 1992) |
| | C37 | Product Literature for Frialit®-2 Implant System, Interpore International and Friatec, 3 pages (1996) |
| | C38 | Gomez-Roman, German, et al., "The Frialit-2 Implant System: Five-Year Clinical Experience In Single-Tooth And Immediately Postextraction Applications," The International Journal of Oral & Maxillofacial Implants, Vol. 12, No. 3, pp. 299-309 (1997) |
| | C39 | Product Literature for Frialit®-2, Abridged Directions For Use, Interpore International and Friatec, 20 pages (believed to be 1996 or 1997) |
| | C40 | "The Influence Of Implant Surface On Hard- And Soft Tissue Integration," Friatec website, 11 pages (written after June 6, 1998) |
| | C41 | Price List, Friatec, 40 pages (October 1998) |
| | C42 | Product Literature for Frialit®-2 Implant System, Friadent, 12 pages (February 1999) |
| | C43 | Price List and Catalog, Friadent, 35 pages (September 2000) |
| | C44 | Product Literature for Frialit®-2, Friadent, 2 pages (believed to be 2000) |

EXAMINER

DATE CONSIDERED

*Examiner: Initial if citations considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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